IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

TAMMIE L. WILLIAMS
7177 Oliver Winchester
Canal Winchester, Ohio 43110

and

CHARLES R. WILLIAMS
7177 Oliver Winchester
Canal Winchester, Ohio 43110

Plaintiffs

vs.

BAUSCH & LOMB COMPANY
Robert B. Stiles, Esq., Statutory Agent
One Bausch & Lomb Place
Rochester, New York 14604

and

pSivida USA, Inc.
c/o Corporation Service Company, Statutory Agent
84 State Street
Boston, Massachusetts 02109

and

David G. Callanan, M.D.
c/o Texas Retina Associates
1001 Waldrop, Suite 512
Arlington, Texas 76012

and

Case No. 2:08 cv 910

Judge JUDGE SMITH

MAGISTRATE JUDGE KEMP

JURY DEMAND
ENDORSED HEREON

Texas Retina Associates :
1001 Waldrop, Suite 512
Arlington, Texas 76012 :

and :

John Doe, Unknown Corporation A, :
Address unknown at this time
:

and

John Doe, Unknown Corporation B, :
Address unknown at this time
:

Defendants

COMPLAINT

I. Preliminary Statement

1. This action seeks compensatory and punitive damages; and costs and attorneys' fees for the bodily injuries, pain and suffering and emotional distress suffered by Plaintiffs as a result of the defective product that Defendants produced and marketed; and for the Defendants' intentional infliction of emotion distress upon Plaintiff.

II. Jurisdiction

2. This action arises under Ohio Revised Code Chapter 2307 and the common law of the State of Ohio.

3. Jurisdiction over the claims is invoked pursuant to this Court's diversity jurisdiction and over the state law claims pursuant to this Court's pendent jurisdiction. The matter in controversy also exceeds, exclusive of interest and costs, the sum specified by 28 U.S.C. §1332.

III. Venue

4. This action properly lies in the United States District Court, Southern District, Eastern Division, pursuant to 29 USC §1391(b), because the claims arose in this judicial district.

IV. Parties

5. Plaintiff, Tammie L. Williams, is and was at all relevant times, a citizen and resident of the City of Columbus, Franklin County, Ohio.

6. Plaintiff, Charles R. Williams, is and was at all relevant times, a citizen and resident the City of Columbus, Franklin County, Ohio. He is the husband of Plaintiff, Tammie L. Williams.

7. Defendant, Bausch & Lomb Company, is and was at all relevant times, a company in the business of designing, manufacturing and distributing optometric devices, including the Retisert Intravitreal Fluocinolone Acetonide Implant at issue in this matter, with its principal place of business in Rochester, New York.

8. Defendant, pSivida Company, is and was at all relevant times, a company in the business of designing, manufacturing and/or distributing the Retisert Intravitreal Fluocinolone Acetonide Implant at issue in this matter, and/or an agent of Bausch & Lomb Company, with its principal place of business in Watertown, Massachusetts.

9. Defendant, David G. Callanan, is a medical physician who acted on behalf of Bausch & Lomb Company, as its agent, principal investigator and study doctor, by surgically placing the Retisert Intravitreal Fluocinolone Acetonide into Plaintiff's eye as part of the study protocol, but failed to warn Plaintiff of the true safety concerns with the implant.

10. Defendant, Texas Retina Associates, is the association for which Defendant Callanan was working at the time of the implant surgery, when he acted as Defendant, Bausch & Lomb Company's agent, principal investigator and study doctor, by surgically placing the Retisert Intravitreal Fluocinolone Acetonide into Plaintiff's eye.

11. John Doe Defendants A and B, are or were suppliers, distributors and/or manufacturers of the Retisert Intravitreal Fluocinolone Acetonide Implant and/or, at all relevant times, are or were agents, officers and representatives of Defendant, Bausch & Lomb, and/or were, at all times material hereto, acting in their individual and official capacities but whose identities are unknown at this time.

V. Facts

12. On or about May 21, 2001, Plaintiff, Tammie L. Williams, agreed to participate in a clinical research study sponsored by Defendants, Bausch & Lomb, Inc., hereinafter referred to as Bausch & Lomb.

13. As part of the research study, Plaintiff agreed to have a "Retisert Intravitreal Fluocinolone Acetonide Implant" surgically implanted into her right eye for the treatment of Uveitis affecting the posterior segment of the eye.

14. A Retisert Intravitreal (inside the vitreous chamber of the eye) Fluocinolone Acetonide (anti-inflammatory drug) Insert is an implant that is surgically implanted into the back of the eye that releases an anti-inflammatory drug to reduce the swelling of certain tissues in the eye (uveitis).

15. Defendants placed its Retisert Implant, hereinafter the "Affected Product" into the stream of worldwide commerce, interstate commerce and into Plaintiff's right eye without adequate testing and with no warning that the Affected Product was subject to

breakage, was defective, inherently dangerous and was unfit for its intended use as described herein due to its potential to break and come apart while in the eye.

16. Plaintiff also was advised, prior to permitting the Affected Product to be implanted into her eye that the implant was to be permanent and could safely remain in her eye permanently.

17. Plaintiff signed a consent form on or about May 21, 2001 permitting the Affected Product to be implanted into her eye; however, the consent form and documentation did not provide any warning or make any mention of the implant's susceptibility to breakage, nor the harmful affects of breakage or separation of the implant while in the eye. The implant was surgically placed into Plaintiff's right eye on or about May 21, 2001 by David G. Callanan, M.D. at his office in Arlington, Texas.

18. Defendant Callanan and his medical practice, Defendant, Texas Retina Associates, acted as agents of Bausch & Lomb Company, as a result of Defendant Callanan's involvement as the principal investigator and study doctor on behalf of Bausch & Lomb Company, regarding the implantation of the Affected Product into Plaintiff's eye.

19. After the implant surgery and having the implant in her eye for a period of thirty (30) months, Defendant, Bausch & Lomb contends, and Plaintiffs deny, that a second consent form was presented to Plaintiff on or about November 6, 2003. This second consent form indicates that "a separation of the cup" (which holds the drug pellet) from the "strut" (which holds the implant in place in the back of her eye) has been observed in a few study patients that had had the implants for over 18 months". But, rather than indicating the true safety hazard and potential harm and serious consequences that could occur from

breakage, it was indicated that "if this does occur, it is unlikely that the eye would feel any discomfort nor should you anticipate any serious or otherwise severe affects to occur".

20. On or about October 6, 2006, while Plaintiff was a resident of Columbus, Franklin County, Ohio, the Affected Product broke and separated while in Plaintiff's eye.

21. The breakage caused major pain, blurred vision, and discomfort for Plaintiff, and required the immediate removal of the broken particle to prevent further pain, discomfort and injury. Shortly after the surgery to remove the broken product, Plaintiff experienced excruciating pain, no vision and other difficulties.

22. Prior to the removal, Plaintiff had vision in her right eye. However, because of the poor condition of her eye prior to removal, and the fact that the condition of her eye with Uveitis, at the time the affected device was implanted indicated that any additional surgeries to her eye could be harmful; when the breakage occurred and had to be removed, this placed Plaintiff's right eye in grave jeopardy.

23. As such, on or about October 9, 2006, immediately after removal of the broken part from her eye, Plaintiff suffered the complete loss of all vision in her eye. Prior to the breakage, Plaintiff had vision in her right eye and could see. After removal of the particle from the Affected Product, Plaintiff lost complete vision in her right eye, and continues to experience total blindness in her right eye, and will suffer such loss permanently.

24. As a result of the Affected Product's breakage, Plaintiff has lost total vision in her right eye, has suffered excruciating pain and discomfort, has suffered economic damages, and serious emotional trauma.

First Claim for Relief – Strict Liability

25. Plaintiff restates and incorporates, as if fully rewritten herein, the statements contained in paragraphs one (1) through twenty four (24) of this Complaint.

26. The Affected Product manufactured and supplied by Defendants was defective in manufacture or construction, in that, when it left the hands of said Defendants, it deviated in a material way from its manufacturing performance standards and/or it differed from otherwise identical units manufactured to the same design formula.

27. The Affected Product manufactured and supplied by Defendants was defective in design and/or formulation in that, when it left the hands of said Defendants, the foreseeable risks exceeded the benefits associated with the design and/or formulation.

28. Alternatively, the Affected Product supplied by Defendants was defective in design and/or formulation in that it was more dangerous than an ordinary consumer would expect when used in its intended or reasonably foreseeable manner.

29. The Affected Product manufactured and/or supplied by Defendants and surgically implanted into Plaintiff's eye by Defendants Callanan and Texas Retina Associates was defective due to inadequate warning or instruction in that, when it left the hands of said Defendants, Defendants knew or should have known that the product was such as to create a risk of harm to Plaintiff, other study participants, and consumers and Defendants failed to exercise reasonable care to warn of said risk.

30. The Affected Product manufactured and/or supplied by said Defendants was defective due to inadequate post-marketing warnings and/or instructions in that, when it left the hands of Defendants, Defendants knew or should have known the risk involved with the

use of said product and failed to exercise reasonable care to provide an adequate warning to users of the product.

31. As a direct and proximate result of the defective condition of the Affected Product as manufactured by said Defendants and placed in Plaintiff's eye, Plaintiff suffered and will continue to suffer risk of disability, expense and economic loss as previously described. Defendants are strictly liable for said damages

Second Claim for Relief – Negligence

32. Plaintiff restates and incorporates, as if fully rewritten herein, the statements contained in paragraphs one (1) through thirty one (31) of this Complaint.

33. Defendants had a duty to exercise reasonable care in the manufacture, design and/or supply of the Affected Product into the stream of commerce and into Plaintiff's eye, including a duty to exercise care to assure that the product was safe for its intended use by study participants and consumers. Defendants maliciously, recklessly and/or negligently failed to exercise ordinary care in the manufacture, testing, design and/or supply of the Affected Product into the stream of worldwide commerce.

34. Defendants maliciously, recklessly and/or negligently failed to exercise reasonable care in the provision of an adequate warning as to the risks of the Affected Product that they knew or should have known.

35. Defendants maliciously, recklessly and/or negligently failed to exercise reasonable care in the post-marketing warnings as to the risks of the Affected Product when it knew or should have known of said risks.

36. As a direct and proximate result of Defendants' malicious, reckless and/or negligent conduct, Plaintiff suffered and will continue to suffer injury, total loss of vision in

her right eye, disability, expense, harm, emotional distress and economic loss as previously described rendering Defendants liable for punitive as well as compensatory damages.

Third Claim for Relief – Breach of Implied Warranty

37. Plaintiff restates and incorporates, as if fully rewritten herein, the statements contained in paragraphs one (1) through thirty six (36) of this Complaint.

38. Defendants are in the business of manufacturing and/or supplying and/or placing into the stream of commerce the Retisert Intravitreal Fluocinolone Acetonide Implant for consumer use.

39. By placing the Affected Product into the stream of commerce, said Defendants impliedly warranted that the Affected Product was fit and safe for its intended use.

40. The Affected Product placed into the stream of commerce by said Defendants was defective in that it was not fit and safe for its intended use.

41. The defect in the Affected Product manufactured and/or supplied by said Defendants was present at the time the product left the hands of said Defendants.

42. Defendants breached the implied warranty for the Affected Product because said product was defective, unmerchantable and not fit for its intended use.

43. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff suffered and will continue to suffer injury, total loss of vision in her right eye, disability, expense, harm, emotional distress and economic loss as previously described rendering Defendants liable for punitive as well as compensatory damages.

Fourth Claim for Relief – Breach of Express Warranty

44. Plaintiff restates and incorporates, as if fully rewritten herein, the statements contained in paragraphs one (1) through forty three (43) of this Complaint.

45. Defendants expressly warranted to Plaintiff that the Affected Product which it designed, developed, manufactured, supplied and sold was of merchantable quality, fit and safe and otherwise not injurious to the Plaintiff's health and well being.

46. The Affected Product placed in Plaintiff, Tammie L. Williams' eye was unsafe, unmerchantable, unfit for use in the body, and otherwise injurious to Plaintiff.

47. Through its sale and use of the Affected Product in the research study, Defendants were merchants pursuant to §2-314 of the Uniform Commercial Code.

48. Defendants breached express warranties of merchantability in the use of the Affected Product in research studies and sale of the product in that said product was not fit for its ordinary purposes described above.

49. As a direct and proximate result of Defendants' breach of its express warranties as described herein, Plaintiffs were caused to suffer substantial and severe harm, injury and damage.

Fifth Claim for Relief – Negligent Misrepresentation

50. Plaintiff restates and incorporates, as if fully rewritten herein, the statements contained in paragraphs one (1) through forty nine (49) of this Complaint.

51. Defendants negligently and carelessly made misrepresentations that the product was safe and would not cause harm without a reasonable basis thereto and did not possess information on which to accurately base those representations.

52. Defendants were aware that they did not possess information on which to accurately base the foregoing representations and concealed from Plaintiff that there was no reasonable basis for making said representations herein.

53. When Defendants made the foregoing representations, they knew or should have known them to be false.

54. In reliance upon the foregoing representations by Defendants, Plaintiff, Tammie L. Williams, did subject herself to the use of the aforementioned product. If Plaintiff had known of the true facts, she would not have taken such action and risk. The reliance of Plaintiff on Defendants' misrepresentations and omissions was reasonable because said representations were made by individuals and entities who are in a position to know the true facts.

55. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Sixth Claim for Relief – Intentional Infliction of Emotional Distress

56. Plaintiff restates and incorporates, as if fully rewritten herein, the statements contained in paragraphs one (1) through fifty five (55) of this Complaint.

57. Plaintiff alleges that Defendants should have known as a result of their designing, manufacturing, distributing and/or surgically implanting the Affected Product in Plaintiff's eye, that their actions would cause Plaintiff serious emotional harm.

58. The conduct of Defendants in designing, manufacturing, distributing and/or surgically implanting the Affected Product in Plaintiff's eye with knowledge of the potential harmful effects of the Affected Product as set out above, has inflicted emotional distress upon Plaintiff and she has suffered mental anguish and depression as a result of the

conduct of Defendants.

59. Such actions of Defendants constitute ill will, malice, extreme and outrageous conduct and were committed intentionally, recklessly and without regard to Plaintiff's rights.

Seventh Claim for Relief - Loss of Consortium

60. Plaintiff restates and incorporates, as if fully rewritten herein, the statements contained in paragraphs one (1) through fifty eight (58) of this Complaint.

61. Further, as a direct and proximate result of the Defendants' malicious actions, negligence, acts and omissions as set forth above, Plaintiff, Charles R. Williams, has suffered loss of the care, companionship and consortium of his wife, Plaintiff, Tammie L. Williams, from the October 8, 2005 to the present, and continuous.

VI. Prayer for Relief

WHEREFORE, Plaintiffs demands judgment against Defendants as follows:

a. For general damages in an amount in excess of ***One Hundred Thousand and 00/100 ($100,000.00) Dollars***;

b. For special damages in an amount in excess of ***One Hundred Thousand and 00/100 ($100,000.00) Dollars***;

c. For exemplary and punitive damages in an amount to be proven at trial, and sufficient to punish Defendants and to deter it and others from repeating the injurious conduct alleged herein;

d. For pre-judgment and post-judgment interest on the above general and special damages;

e. For restitution and disgorgement of profits;

f. For costs of this suit and attorneys' fees; and

g. For all other relief that Plaintiffs may be entitled to at equity or at law, including but not limited to the funding of a medical monitoring program.

RENNY J. TYSON CO., LPA

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JURY DEMAND

Plaintiff demands a trial of this cause by jury.

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